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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/636,081

08/06/2003

Pramod K. Gupta

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05/19/2010

WEYERHAEUSER COMPANY  
INTELLECTUAL PROPERTY DEPT., CH 1J27  
P.O. BOX 9777  
FEDERAL WAY, WA 98063

EXAMINER

PARA, ANNETTE H

ART UNIT

PAPER NUMBER

1661

NOTIFICATION DATE

DELIVERY MODE

05/19/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@weyerhaeuser.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/636,081	<b>Applicant(s)</b> GUPTA ET AL.	
	<b>Examiner</b> ANNETTE H. PARA	<b>Art Unit</b> 1661	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13, 17-19, 21 and 23-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 17-19, 21 and 23-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

The previous office action sent out on 05/11/2010 is vacated in favor of this office action.

The finality of the office action sent on January 4, 2010 has been withdrawn.

#### *Listing of the Claims*

Claims 1-13, 17-19, 21, and 23-26 are examined. Claims 14-16, 20 and 22 have been cancelled.

#### *Claim Rejections - 35 U.S.C. §103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

35 U.S.C. §103(a).

The *Graham* court set forth the factual inquiries that are applied for determining obviousness under 35 U.S.C. 103(a):

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

*Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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**Claims 1-13, 17-19, 21, 23-26 remain rejected under 35 U.S.C. 103(a)** as being unpatentable over Pullman et al. (US 5,294,549 published on March, 15 1994) in view of Gupta (US 5,563,061 1996).

The claims are drawn to a method for producing conifer somatic embryos by cultivating pre-cotyledonary cells in a medium comprising nutrient wherein the osmolality is from 180 mM/Kg to 400 mM/Kg then transferring them to a synchronization medium comprising abscisic acid, gibberellin, maltose as the principal sugar source and activated charcoal as an absorbent for a period of .5 week to 5 weeks. And finally, transferring the pre-cotyledonary somatic embryos to a development medium for a period from 9 to 14 weeks to produce cotyledonary somatic embryos.

Pullman et al teach a method of cultivating conifer pro-cotyledonary somatic embryos in a maintenance medium comprising nutrients that sustain the embryos. The maintenance medium has an osmolality of 170mM/Kg to about 240 mM/Kg (column 15, lines 1-3). The pro-cotyledonary are then transferred to a liquid singulation (synchronization) medium comprising gibberellin and/or abscisic acid at concentrations of 0.05 and 15 mg/L (col. 13, lines 40-60) and comprising also activated charcoal (col. 13, lines 50-54), for at least 3 weeks (col. 15, lines 23-26). This medium has a reduced osmotic level compared to the one of the maintenance medium, thus less than 170 mM/Kg (column 15, lines 13-14). Finally, the pro-cotyledonary embryos are transferred to a development medium wherein the osmolality is above about 400 mM/Kg (col. 15, line 60). Pullman et al. also teach the use of activated charcoal at a concentration of 2.5g/L (Table 2). Further Pullman et al. teach media with a pH of 5.7 (Table 1). . Pullman et al. teach that this method can be used for many species including loblolly pine (col. 7, lines 50-60).

Pullman et al. is silent in the time frame period claimed in step (c) and but the amount of time the embryos are kept on the development medium is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal time the embryos have to be kept on the development medium to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of time would have been obvious at the time of Applicant's invention.

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Although none of the references teach that the method used produces 50% or 75% of the embryos population at the same developmental stage produced by the instant method, it would be known that by using known media and other well-known medium additives, it would be obvious that one skilled in the art would have obtained 50% or 75% of the embryos population at the same developmental stage.

None of the references teach a solid singulation (synchronization) medium but the use of a solid medium is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of time would have been obvious at the time of Applicant's invention.

Pullman et al. fail to teach a singulation (synchronization) medium comprising maltose as the principal sugar source.

However,

Gupta teaches a singulation (synchronization) medium comprising maltose as the principal sugar source.

At the time the invention was made it would have been obvious for one of ordinary in the art to modify the method of Pullman et al. by using maltose as the principal sugar source in the singulation (synchronization) medium. One of ordinary skill in the art would have been motivated to use maltose as the principal sugar source in the singulation medium knowing that it "results in stronger embryos that, in turn, produce more robust cotyledonary somatic embryos having close similarity to zygotic embryos" (US 5,563,061 column 7, lines 45-55). Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Comment

No claims are allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette H. Para whose telephone number is (571) 272-0982. The examiner can normally be reached Monday through Thursday from 5:30 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975. The fax number for the organization where the application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Annette H Para/

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Primary Examiner

Response to Applicants' arguments

Applicants' arguments filed on 04/05/2010 have been fully considered, but they are not persuasive.

Applicants argue that Pullman does not teach or suggest cultivating pre-cotyledonary embryogenic cells for a period from one week to two weeks in, or on a synchronization medium, as recited in Claim 1 step (b). In contrast to the claimed invention, Pullman discloses a culturing step referred to as "singulation" for Douglas-fir. See Pullman et al. at Col. 8, lines 18-21. Pullman et al. teaches the transfer of pre-cotyledonary Douglas-fir somatic embryos from a maintenance medium to a singulation medium for at least three weeks, followed by transfer to a development medium. As described in Examples 1-7, which are directed to methods for improving Douglas-fir embryo development, "Late stage Douglas-fir proembryos were singulated in a three step liquid shake culture as outlined above." Example 2 at Col. 15, line 68, to Col. 16, line 2. As described in Example 1, a preferred schedule for the singulation step in Douglas-fir is "one week on a medium containing 10mg/L ABA, a second week on a medium containing 5mg/L ABA, and a third week on a medium also with 5mg/L ABA." Col. 15, lines 10-27. It is further noted that Pullman does not teach or suggest the use of a medium that comprises maltose as the principal metabolizable sugar source, an absorbent composition and at least one synchronization agent selected from the group consisting of abscisic acid and a gibberellin, as claimed.

It is noted that Gupta does not teach or suggest cultivating pre-cotyledonary pine embryogenic cells for a period from one week to two weeks in, or on a synchronization medium, as recited in Claim 1 step (b). Rather, in contrast to the claimed invention, Gupta et al. teaches that Douglas-fir requires an intermediate singulation culturing step between early stage embryo growth and the final development stage due to the formation of tight clusters of embryos. As described in Gupta, singulation is carried out in a series of liquid shake cultures lacking auxins and cytokinins but which have exogenous abscisic acid added as a necessary new hormone. Gupta at Col. 8, lines 4-9. 'All of the claimed elements are not found in the cited references. In order to establish a prima facie case of obviousness, all of the claimed elements must be found in the prior art. See M.P.E.P. § 2143. As discussed supra, both Pullman, and Gupta teach a culturing step referred to as "singulation" for Douglas-fir in which pre-cotyledonary Douglas-fir somatic embryos from a maintenance medium to a singulation medium for at least three weeks, followed by transfer to a development medium. Neither Pullman or Gupta teach or provide any suggestion regarding culturing pre-cotyledonary pine Embryogeny cells in synchronization medium for from one to two weeks, as recited in step (b) of Claim 1. Accordingly, because neither of the cited references provides any teaching regarding the synchronization of pre-cotyledonary pine embryogenic cells, and in particular, the cultivation of pre-cotyledonary pine embryogenic cells for a period of one to two weeks in synchronization medium as claimed, the cited references alone or in combination do not teach or suggest every element of Claim 1. No motivation to modify the teachings of Pullman and/or Gupta to arrive at the claimed invention There is no suggestion or motivation provided in either Pullman or Gupta to modify the teachings of the cited references, which are both directed to singulation in Douglas-fir, in order to arrive at the claimed invention, which is directed to synchronization of pine pre-cotyledonary embryos. As noted supra, the step of singulation is carried out during Douglas-fir embryogenesis due to the formation of tight clusters of Douglas-fir embryos. As described in the cited references, the step of singulation in Douglas-fir is carried out for at least three weeks in a series of liquid shake cultures. See Gupta at Col. 8, lines 4-9; and Pullman et al. at Col. 8, lines 18-21. There is no suggestion or motivation provided in either reference to modify the teachings to reduce the time of incubation in singulation medium to 1 to 2 weeks, as claimed, because the proposed modification would likely render the methods of the cited references inoperable, or at least less efficacious, for their intended purpose of singulation. Moreover, it is further noted that the Examiner admits that neither Pullman nor Gupta teach or remotely suggest synchronization of embryos. As described in the present specification, the claimed invention is based on the discovery by the present inventors that culturing pine embryos in a synchronization medium that comprises maltose as the principle metabolizable sugar source, an absorbent composition (e.g., activated charcoal) and at least one of abscisic acid and a gibberellin for one to two weeks prior to incubation in development media inhibited precocious embryo development and greening, while promoting synchronization of the cultures, thereby resulting in embryos very uniform in size in comparison to control cultures. Specification at page 19, lines 19-31; page 16, lines 26-30; and Tables 1 and 2. As further described in the instant specification, it was experimentally determined that in the absence of the step of culturing in a synchronization medium (i.e., control cultures grown in maintenance medium and directly transferred to development medium, similar to Examples 8 and 9 of Pullman et al.), the resulting cultures were not synchronized, and contained embryos that were cleaving, growing, and forming embryo suspensor masses, with embryos seen in many different stages. Specification at page 19, lines 1-5.

These arguments are not found persuasive because Pullman et al. teach culturing of proembryos in a maintenance medium then transferring the late proembryos in a singulation medium comprising active gibberellins and abscisic

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acid and finally transferring these proembryos to an embryo development medium (column 15, lines 5-35).

Pullman et al. state that adding the singulation step is beneficial for improvement of proembryos quality (column 8, lines 5-14). Pullman et al. also teach that “for virtually all coniferous species a supply of exogenous abscisic acid is a useful hormone in the development from proembryos to cotyledonary embryos...this was always used in combination with an absorbent such as activated charcoal.”(column 9, lines 49-55). Pullman et al. then add that the addition of the combination of Gibberelins and Abscisic acid reduces tendency to precocious germination. The singulation step taught by Pullman et al. is identical to the synchronization step as claimed. Thus, the method taught by Pullman et al. is identical to the present method as it comprises every step of the claimed method, and is presumed to inherently possess the same properties. Pullman et al. teach a singulation step (synchronization) which encompass two or three transfers at weekly intervals, which is one to two weeks as claimed (column 8, line 32). The method described in example 1 is for Douglas-fir embryos but earlier Pullman et al. state: It appears now that the inclusion of between 0.05 and 15 mg/L preferably about .1-5 mg/L of selected active gibberellins and abscisic acid in the late proembryo development media is also beneficial for improvement of proembryo quality...These may then transferred to an embryo development medium...(column 8, lines 4-14). Pullman et al also clearly state: species other than Douglas-fir can be advantageously cultured by beginning early cotyledonary embryo development in a series of media similar to those used for Douglas-fir singulation.(column 8, lines 49-52). Pullman et al. is silent about the uniformity in size of the embryos obtained but a reference which is silent about a claimed invention's feature is inherently anticipatory if the missing feature is necessarily present in that which is described in the reference. In re Oelrich, 212 USPQ 323 (CCPA 1981). Pullman et al. is silent in the time frame period claimed in step (c) and but the amount of time the embryos are kept on the development medium is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal time the embryos have to be kept on the development medium to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of time would have been obvious at the time of Applicant's invention.

Although none of the references teach that the method used produces 50% or 75% of the embryos population at the same developmental stage produced by the instant method, it would be known that by using known media and other



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well-known medium additives, it would be obvious that one skilled in the art would have obtained 50% or 75% of the embryos population at the same developmental stage.

None of the references teach a solid singulation (synchronization) medium but the use of a solid medium is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of time would have been obvious at the time of Applicant's invention.

Pullman et al. fail to teach a singulation (synchronization) medium comprising maltose as the principal sugar source. However,

Gupta teaches a singulation medium comprising maltose as the principal sugar source.

All of the claimed elements are either found in the prior art or are optimization of parameters. Moreover, Pullman clearly states that optimization "considered to be within the routine experimental capability of those skilled in the art of tissue culture" (Pullman, col.23, lines 8-10). Applicants have not explained why it would not have been obvious, as asserted by the examiner, to optimize the culture conditions to have achieved the claimed subject matter.